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09/787,922	06/13/2001	Karin Angela Hing	HING3001/REF	8656

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EXAMINER

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ART UNIT	PAPER NUMBER
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1731

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Please find below and/or attached an Office communication concerning this application or proceeding.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 0104

Application Number: 09/787,922
Filing Date: June 13, 2001
Appellant(s): HING ET AL.

Richard E. Fichter
For Appellant

EXAMINER'S ANSWER

MAILED
JAN 14 2004
GROUP 1700

This is in response to the appeal brief filed October 23, 2003.

(1) Real Party in Interest

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A statement identifying the real party in interest is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1-27 and 32-39 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5395722	NUKADA et al.	3-1995
5656562	WU	8-1997
5895897	OISHI et al.	4-1999

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WO 93/04013

DYTECH CORPORATION 3-1993

LIMITED

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-27, 32, 33 and 35-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/04013 in view of Oishi et al. (5,895,897).

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WO 93/04013 teaches the basic claimed process of producing a ceramic foam. The process disclosed by WO 93/04013 includes the steps of:

forming a ceramic slip having a viscosity of 5-1000 mPa.s comprising:

ceramic particulate,
an organic binder,
liquid carrier, and
surfactants

foaming the ceramic slip; and

heating the foamed ceramic slip at a temperature sufficient to substantially burn out the organic binder. WO 93/04013 also discloses the addition of a gas generating substance (item 5, page 8); the use of hydroxyapatite (p.5, line 24); particle sizes of e.g. 5 μm (page 5); the liquid carrier is water (page 6); the addition of a deflocculating agent (page 8, line 20); drying the foam prior to removing binder (Example II); sintering the foam (Example VIII) and porosities of 20 to 95% (page 11, line 8).

WO 93/04013 does not disclose that the slip is foamed using a ball mill but generically discloses that the slip may be foamed mechanically (e.g. page 5, line 4).

Oishi et al. discloses foaming a slip using a ball mill to produce a foam having pore sizes of 100-2000 μm . It would have been obvious to one skilled in the art at the time of the invention to use this method of foaming in view of the generic disclosure of WO 93/04013 to produce articles with the claimed pore sizes.

Determination of the specific particle surface area, ingredient amounts and firing temperatures would have been well within the realm of routine experimentation to one having ordinary skill in the art at the time of the invention. These parameters would have obviously been selected to optimize the process conditions and/or the properties of the final product.

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The use of mold release agents and the claimed binder materials are notoriously well known in the art of molding ceramics. It would have been obvious to use these materials in the process of WO 93/04013 to optimize the process in view of the generic disclosure therein.

Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/04013 in view of Oishi et al. (5,895,897) as applied to claims 1,4-27,32,33 and 35-39 above, and further in view of Wu (5,656,562).

Wu discloses the use of alumina media having a 12.7 mm size for use in a ball mill (col. 5, lines 33-34). It would have been obvious to one skilled in the art at the time of the invention to use this type of media in the process of WO 93/04013 in view of the generic disclosure therein.

Claims 2,3 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/04013 in view of Oishi et al. (5,895,897) as applied to claims 1,4-27,32,33 and 35-39 above, and further in view of Nukada et al. (5,395,722).

Nukada et al. discloses the use of alumina and zirconia media of 1-30mm size for use in a ball mill (col. 5, lines 60-65). It would have been obvious to one skilled in the art at the time of the invention to use this type of media in the process of WO 93/04013 in view of the generic disclosure therein.

(11) Response to Argument

With respect to the rejection of the claims under 35 USC 103, applicants argue:

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Claim 1 on appeal is directed to "A method of producing a synthetic bone material for use in biomedical applications, the synthetic bone material comprising a macroporous ceramic foam which has an open foam structure containing pores with a modal diameter $d_{\text{mode}} \geq 100 \mu\text{m}$...". Thus, the claimed method is concerned with making a synthetic bone material for biomedical applications (see page 1, lines 1 to 5 of Applicants' specification). There is no specific teaching of this limitation in WO 93/04013 (hereinafter the primary reference) where there is only a passing teaching to "artificial parts for the body" at page 10 of this reference, as a possible product to be formed from a list of more than twenty diversely different products.

This argument is not persuasive. It is submitted that the teaching of artificial parts for the body (WO 93/04013, page 10, lines 10-11) encompasses synthetic bone material. Clearly porous ceramics as disclosed by the primary reference would be used to replace bone, as is conventionally done in the art, as opposed to replacing skin or other soft tissues. The primary reference further discloses the use of hydroxyapatite which is a bioceramic conventionally used to produce synthetic bone (see e.g. Appeal Brief, page 9, third line from bottom).

As used in the claims on appeal, the term "macroporous" means an open foam structure containing pores with a modal diameter $d_{\text{mode}} \geq 100 \mu\text{m}$ (see Applicants' specification on page 4, lines 14 to 17). This is a claim limitation which cannot be ignored and is not described or suggested in the primary reference.

This argument is not persuasive. Clearly, this limitation was not ignored by the examiner. The rejection of the claims includes the following language: "Oishi et al. discloses foaming a slip using a ball mill to produce a foam having pore sizes of 100-2000 μm . It would have been obvious to one skilled in the art at the time of the invention to use this method of foaming in view of the generic disclosure of WO 93/04013 to produce articles with the claimed pore sizes." One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

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There is no positive teaching in the primary reference of the open pore structure which is a claim limitation of all of the claims on appeal.

This argument is not persuasive. The primary reference states that the pores may be closed and/or the porosity may be open at page 11, second full paragraph.

Applicants note that the primary reference does refer to gas entrapment by mechanical means and suggests that this may be achieved simply by stirring. This is exemplified in Examples WX, where a paddle stirrer or stirring in a beaker was used. The other Examples (Example I-IV) rely on a Buchner funnel to produce the foam. It is therefore clear that one of ordinary skill in the art would appreciate that the primary reference had identified what it considered to be suitable methods for forming a foamed ceramic. There is no indication in the primary reference that there were any problems associated with these foaming methods. Accordingly, there simply would not be any motivation for a person skilled in the art to look elsewhere for an alternative foaming technique.

This argument is not persuasive. The primary reference teaches that foaming or gas entrapment can be carried out by mechanical means (page 5, line 4 and page 7, item #1) or other means (pages 7-8). It is agreed that the primary reference gives examples including stirring and using a Buchner funnel, but the primary reference is not limited to the use of these exemplary methods. It is maintained that one skilled in the art would be motivated to look to a reference such as Oishi et al. for mechanical means of foaming ceramic slurries in view of the teaching of the primary reference. It is well settled that a reference must be considered for not only what it expressly teaches, but also for what it fairly suggests and that the entirety of the reference disclosure, including unpreferred embodiments must be considered in determining obviousness.

In re Burckel 592 F.2d 1175, 201 USPQ 67; *In re Lamberti* 545 F.2d 747 USPQ 278.

It is clear that '897 lies in a completely different technical field from that of the present invention, i.e. synthetic bone materials for biomedical applications. Applicants most respectfully submit that the skilled person, seeking to improve the properties of a ceramic foam for biomedical applications, would not modify the disclosure of the primary

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reference based on the teaching of the '897 patent related to forming an acoustic absorber to obtain the presently claimed invention. In particular, there is no suggestion in either the primary reference or the '897 patent that the use of a ball mill to achieve foaming of a ceramic slip would result in an improved biomedical ceramic material. Accordingly, there would be no motivation for the skilled person to combine the teachings of the primary reference with the '897 patent, absent Applicants' teaching. In re Fritch, 23 USPQ 1780, 1784(Fed Cir. 1992) ("It is impermissible to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps.). Moreover, obvious to try is not the standard of obviousness under 35 USC 103(a).

This argument is not persuasive. The fact the product produced by the '897 reference is different from the claimed product does not mean that they are in different technical fields. Both deal with foaming ceramic slurries and thus they are indeed in the same technical field. Further, the motivation to combine the reference need not suggest arriving at the claimed invention. The fact that the primary reference suggests mechanical foaming of a ceramic slurry and the '897 patent discloses a method for mechanical foaming is motivation to combine the references. It is not required to show that the references suggest that an improved biomedical ceramic material would result. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *In re Keller* 208 USPQ 871, 881; *In re Sernaker* 217 USPQ 1.

There is also no indication that the ceramic according to the '897 patent has an open macroporous structure with a modal pore size > 100 μm , as required by claim 1 on appeal.

This argument is not persuasive. Col. 8 of the '897 patent discloses pore sizes up to 5000 μ contained in the body of the sintered product. Thus, it would be difficult to have a modal

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pore size of less than 100 (i.e. one that lies outside the claimed range). '897 also discloses at col. 8, line 21 that the voids are continuous.

It is further noted that teachings of the primary reference and the '897 patent appear to be inconsistent with respect to the feature of claim 1 on appeal that the foamed macroporous ceramic material exhibits open porosity and has a modal pore size $\geq 100 \mu\text{m}$. Indeed, the reference to the Buchner funnel in Examples II, III and IV of the primary reference would be expected to result in pores having a similar size to that of the filter, i.e. 10 to 16 μm . Example VIII using hydroxyapatite and ultrasonic agitation yields a product having a pore diameter of 24 μm . The Examiner appears to acknowledge that all of the examples in the primary reference that rely on stirring (i.e. mechanical means) to introduce the gas are silent with respect to pore size. The Examiner then suggests that because the primary reference mentions that the porous articles may be used in artificial parts for the body that they would necessarily have the required pore size but gives no basis for this conclusion. This statement is specifically traversed. It is without factual support in any reference or based on sound scientific reasoning.

This argument is not persuasive. First it is maintained that the '897 reference discloses pore sizes which meet the claimed range. Thus, the rejection is based on factual support.

Applicants state "The Examiner then suggests that because the primary reference mentions that the porous articles may be used in artificial parts for the body that they would necessarily have the required pore size". This statement is inaccurate. Although the final rejection states "the materials are suitable for artificial parts of the body" there is no statement that they would necessarily have the required pore size.

As noted on page 6 of Applicants' specification the organic binder serves to provide plasticity during forming of the ceramic particulate and green strength in the formed product. It is also noted that all of the examples in Applicants' specification include an organic binder. At page 7, line 5, of Applicants' specification, it is stated that the organic binder will generally be present in a liquid carrier in an amount of from 0.2 to 10 w/v% and more preferably from 0.5 to 6 w/v%. The specific and preferred limitations are specifically set forth in claims 12, 13 and 35 on appeal. There is absolutely no suggestion in the prior art of these specific ranges which are claim limitations. The necessary motivation is not in the prior art to suggest these preferred aspects of the presently claimed invention and for this reason, these claims are further distinguished over the prior art.

The only disclosure in the primary reference to the use of a binder is at page 9 which simply suggests that binders such as resins may be included but there is no

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suggestion of the specified amounts which are clearly indicated to be preferred embodiments of the presently claimed invention. The examples in the primary reference do not use binders let alone suggest the amounts specified in claims 12, 13 and 35. While the '897 patent describes the use of an organic binder in the paragraph beginning at column 3, line 25, this relates to a foam slurry which is produced by mixing an alumina based ceramic powder, SiC whiskers, and a solution containing a dispersant, an organic binder and a foaming agent in water. This in no way suggests a modification of the primary reference to arrive at the presently claimed preferred binder concentrations as claimed in claims 11, 12 and 35 on appeal.

As discussed at page 20 of Applicants' specification, the results in Table 3 and Figures 7-10 demonstrate how variation in the ratio of ceramic particulate to binder solution variation in both the bulk density (macro-porosity) and the strut density (micro-porosity). The sintered mill-foamed porous ceramics prepared with the greater volume of liquid carrier have lower bulk and strut densities reflecting a more open, inter-connected pore structure with large macro-pores and a larger fraction of micro-porosity. As noted at page 21, the macro-porous ceramic foams according to the present invention have advantages over the prior art cancellous and coral derived materials.

This argument is not persuasive. As mentioned by applicant the primary reference teaches the use of a binder, but is silent with respect to amount of binder used. Thus, the amount of binder is left to be determined by one of ordinary skill in the art. The examiner further indicated in the office action that: "Determination of the specific particle surface area, **ingredient amounts** and firing temperatures would have been well within the realm of routine experimentation to one having ordinary skill in the art at the time of the invention. These parameters would have obviously been selected to optimize the process conditions and/or the properties of the final product." Changes in temperature, concentrations or other process conditions of an old process within the broad teaching of the prior art does not impart patentability in the absence of an unexpected result. *In re Aller*, 220 F.2d 454, 105 USPQ 233 (CCPA 1955). The results from applicants specification discussed above are not unexpected. Table 3 on page 20 of the specification shows that the density of the ceramic is reduced with an

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increase in binder. This is not unexpected. As more binder is added, more void space is created upon firing, leading to decreased densities.

The sintered ceramic foam has a bulk porosity in the range of from 70 to 90% as specifically claimed in claim 37 and a slightly broader range in claim 25. These are specific claim limitations which again are in no way suggested by the prior art. The strut density is specified in claims 26 and 38. Clearly, these limitations are present in the claims, discussed in the specification, and further distinguish the claimed subject matter over the prior art.

This argument is not persuasive. WO 93/04013 discloses the production of bodies having porosity of about 20 to about 95% which encompasses the claimed values.

In the Final Rejection, the Examiner states that '562 patent is cited to teach a conventional size of grinding media. However, claim 2 on appeal is not concerned with milling powders using a grinding media. Instead, claim 2 is concerned with foaming a ceramic slip in a ball mill. This differs from the teaching of the '562 patent in that the starting material is a ceramic slip (not a starting powder) and in that the process produces a foam (not a milled powder). These are fundamental differences as would be appreciated by one of ordinary skill in the art to which the invention pertains. As the Examiner has acknowledged, the '562 patent is not concerned with foamed ceramics, nor synthetic bone materials for biomedical applications.

Applicants note that dependent claim 3 defines that the milling media have a diameter in the range of from 10 to 30 mm. This range is not disclosed in the '897 patent. While the '562 patent does mention 13 mm milling media, this is for grinding the starting powder, not for foaming a ceramic slip. There is no teaching or suggestion in any of the documents that such sized milling media could or should be relied on in the formation of a ceramic foam in accordance with the requirement of claim 3, let alone a ceramic foam for a synthetic bone material, where the pores have a modal diameter as specified by the claims on appeal.

The '562 patent relates to a method of improving the properties of ceramic green bodies. While the '562 patent does mention the use of a ball mill, this is not used to prepare a foamed ceramic. Instead, the ball mill is merely used to prepare (i.e. mill) the starting powders. This is clear from column 5, lines 31 to 42, where, the powders are milled and then separated from the grinding media. Only then is a slurry formed by adding deionized water. Thus, the '562 patent merely describes the conventional technique of using grinding media to mill starting powders. The '562 patent is not concerned with foamed ceramics, nor synthetic bone materials for biomedical applications. In view of the above comments, it is considered that the disclosure of the '562 patent has been taken out of context and does not establish a prima facie case of obviousness for the claimed subject matter and this rejection should be reversed.

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This argument is not persuasive. As stated in the rejection, the '562 patent is relied upon only to teach the size of the milling media. It is recognized that the media is used for milling in the '562 reference. However, one skilled in the art would look to reference such as the '562 reference to establish the size of media conventionally used in ball mills such as that disclosed in the '897 reference. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *In re Keller* 208 USPQ 871, 881; *In re Sernaker* 217 USPQ 1. It is maintained that the '562 patent suggests the use of media of the claimed size in ball mills.

With regard to the '722 patent, this reference is even further removed relating as it does to a electrophotographic photoreceptor. Even though the '722 patent does mention the use of a ball mill, this is used to prepare (i.e. mill) an organic perylene pigment. The '722 patent has nothing to do with ceramic powders let alone the preparation of a foamed ceramic bone material for biomedical applications. This reference was located by looking for claimed limitations and then searching the prior art for these limitations. This is improper hindsight reconstruction of the prior art to arrive at the claimed invention. Accordingly, the Examiner's rejection should most respectfully be reversed.

This argument is not persuasive. As stated in the rejection, the '722 patent is relied upon only to teach the size of the milling media. It is recognized that the media is used for milling in the '722 reference. However, one skilled in the art would look to reference such as the '722 reference to establish the size of media conventionally used in ball mills such as that disclosed in the '897 reference. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the

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art. *In re Keller* 208 USPQ 871, 881; *In re Sernaker* 217 USPQ 1. It is maintained that the '722 patent suggests the use of media of the claimed size in ball mills.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

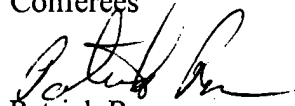
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Christopher A. Fiorilla
Primary Examiner
Art Unit 1731

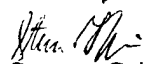
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January 12, 2004

Conferees

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Patrick Ryan

A handwritten signature in black ink, appearing to read 'Steven Griffin', with a large, stylized loop at the end.

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